

# SOPs for the 21<sup>st</sup> Century

## *Why Less Is More*

DEC. 7-8, 2017

COURTYARD ARLINGTON CRYSTAL CITY/  
REAGAN NATIONAL AIRPORT  
ARLINGTON, VA (WASHINGTON, DC)

AN INTERACTIVE WORKSHOP PRESENTED BY CERULEAN LLC AND FDANEWS

## Agenda

### Day 1

**8:30 a.m. – 9:00 a.m.** Registration and Continental Breakfast

**9:00 a.m. – 9:15 a.m.** Introduction and Welcome

**9:15 a.m. – 10:45 a.m.** SOPs and Policies - What's Really Required?

- Core regulatory requirements — FDA, EMA, ISO and more
- Guidances — what you don't know will hurt you
- How to quickly parse warning letters for SOP expectations
- FDA investigator questions to expect about your SOPs and policies
- *Interactive Exercise* — Attendees act as FDA investigators and company personnel to review SOPs to identify the proof FDA expects to see during an inspection to prove the SOP was followed

**10:45 a.m. – 11:00 a.m.** Break

**11:00 a.m. – 12:00 p.m.** Practical Reality — the Business Costs of Poor SOPS and Policies

- Real world business costs of poor SOPs and policies
- Practical quality costs of poor SOPs and policies
- *Interactive Exercise* — Attendees role-play through several case-study SOPs and compare typical SOPs to their modernized, simplified and streamlined versions

**12:00 p.m. – 1:00 p.m.** Lunch

**1:00 p.m. – 2:15 p.m.** Critical SOP Components to Prove Compliance

- Take advantage of the Policy-SOP-Task Outline hierarchy
- Understand the role of adult comprehension and retention
- SOP format and structure for the 21st century — why less is more
- Why every SOP needs to generate a record
- How to use forms, checklists, and templates to reinforce compliance
- Where do definitions belong in the era of wikis and intranets?

- 2:15 p.m. – 2:30 p.m.** Break
- 2:30 p.m. – 4:30 p.m.** Process Mapping
- Why FDA, your staff and your management like to see process maps
  - Why process maps help in the “big picture”
  - Process mapping rules
  - How to process map like a pro
  - Ways in which to use a process map — from training to auditing
  - Sneaky ways to use process maps to achieve 100% compliance
  - *Interactive Exercise* — Attendees work in teams to process map several case study SOPs
- 4:30 p.m. – 5:00 p.m.** Day One Wrap Up and Review
- *Interactive Exercise* — Attendees identify 3 compelling reasons for personnel at their own company why they should update and streamline their SOPs and policies

## Day 2

- 9:00 a.m. – 9:15 a.m.** Day Two Welcome and Quick Learning Recap
- 9:15 a.m. – 10:30 a.m.** SOP Metrics to Prove Effectiveness
- Why metrics are important to a culture of compliance
  - Why management (and FDA) want to see metrics
  - Simple metrics that work for SOPs and policies
  - When to review metrics — and when not to
  - *Interactive Exercise* — Attendees draft a follow-up action plan from several case study SOP metrics to improve compliance
- 10:30 a.m. – 10:45 a.m.** Break
- 10:45 a.m. – 12:00 p.m.** Advanced Tactics to Reduce Overhead and Lighten Your Workload
- How to best use photographs in SOPs
  - Mistakes to avoid in your “SOP of SOPs”
  - Steps to foster self-compliance using self-assessments
  - How to write an SOP to oversee an activity you’ve outsourced
  - The easy — and critical — role for senior management
  - *Interactive Exercise* — Draft a communication to be sent out by your senior team to all company employees about Quality Systems SOPs that will actually lower your workload and encourage self-compliance
- 12:00 p.m. – 1:00 p.m.** Lunch
- 1:00 p.m. – 2:00 p.m.** Writing for the Right Audience
- Tips on writing for a line worker
  - Tips on writing for an office worker
  - Tips on writing for scientists and engineers
  - Tips on writing for management

- *Interactive Exercise* — Attendees analyze and select phrases, words, and document structures best suited to ensuring compliance among different types of workers, managers, and contractors

**2:00 p.m. – 2:15 p.m.** Break

**2:15 p.m. – 3:30 p.m.** Making SOP Training “Sticky”

- How to design a training session for adult information retention
- How to craft engaging slides and other training materials
- Types of SOP hands-on materials for the factory line and the office
- Ways to use training to handle one-off details not in SOPs
- *Interactive Exercise* — Work in teams to outline a sample, hands-on training session for two different SOPs

**3:30 p.m. – 4:00 p.m.** Building Your Business Case to Streamline Your SOPs & Policies

- *Interactive Exercise* — Attendees work with the expert instructor to draft their own personal, business case and prioritized plan for streamlining and modernizing their quality system SOPs and policies

**4:00 p.m. – 4:30 p.m.** Wrap Up and Final Questions

**4:30 p.m.** Adjournment